

## **REMARKS**

Claims 1-2 are pending in the subject application and stand rejected. Claims 3-8 were previously withdrawn.

Applicants thank the Examiner for the courtesies extended to Applicants' representatives in the telephone interview of February 17, 2010.

### **A) Objection to Specification**

A Preliminary Amendment filed on October 20, 2009 has been objected to under 35 U.S.C. 132(a) for introducing new matter into the specification. Specifically, the Examiner asserts (1) that SEQ ID NOS: 17 and 18 set forth on pages 5, 7, and 28 of the amended specification are not supported in the original disclosure, (2) there are discrepancies between SEQ ID NO. 17 and the published sequence for mouse hairless protein, and (3) that there is no support for amendments on pages 27-28 changing nucleotide positions from 2166, 2611, and 2916 to 2165, 2600, and 2915, respectively. Applicants traverse this objection for at least the reasons set forth herein.

1) Applicants submit that SEQ ID NO: 18 represents the C-terminal portion of the genomic sequence of the HR gene (i.e., genomic sequence of HRt) disclosed in Figure 2 of Begona, M. et al., "Structure and Expression of the Hairless Gene of Mice", J. Proc. Natl. Acad. Sci, USA , 1994: 91: 7717-7721 ("Begona"). Applicants further submit that SEQ ID NO. 17 represents the C-terminal portion of the HR protein (i.e., amino acid sequence of HRt) also disclosed in Figure 2 of Begona, which is cited on page 27 and incorporated by reference on page 33 of the originally-filed specification by

the statement, "[a]ll documents cited are, in relevant part, incorporated herein by reference".

As set forth in 37 C.F.R. § 1.57(b), "an incorporation by reference must be set forth in the specification and must (1) express a clear intent to incorporate by reference by using the root words 'incorporate' and 'reference' (e.g., 'incorporate by reference'); and (2) clearly identify the referenced patent, application, or publication". As set forth above, the specification clearly conveys an intent to incorporate the reference on pages 27 and 33 of the originally-filed disclosure and the Begona reference is clearly identified on page 27. Thus, Applicants submit that incorporation by reference of Begona into the specification satisfies 37 C.F.R. § 1.57(b)(1) and (2). There is nothing in Rule 1.57(b) that requires the expression of the intent to incorporate by reference to be positioned immediately following the clear identification of the referenced publication

Accordingly, Applicants submit that the C-terminal portion of the genomic sequence of the HR gene represented by SEQ ID NO: 18 and the C-terminal portion of the HR protein represented by SEQ ID NO: 17 do not constitute new matter because both sequences are disclosed in Begona, which was properly incorporated by reference under 37 C.F.R. § 1.57. Hence, Applicants respectfully request withdrawal of the objection to SEQ ID NOS: 17 and 18 and entry of the amendments filed on October 20, 2009.

2) The Examiner asserts that "an inspection of the sequences provided by the Applicant and the sequences known in the art as mouse hairless protein indicates that the sequence provided by Applicant is not amino acid residues 490-1182 of mouse

hairless protein" (Office Action, page 3). The Examiner further asserts that SEQ ID NO: 17 is only 99.4% identical to the amino acids 490-1182 of I48378, which is 100% identical to the GenBank Accession No. Z32675 (Office Action, page 3).

Applicants submit that the amino acid sequence of SEQ ID NO: 17 is translated from the C-terminal portion of the genomic sequence of the HR gene (i.e., SEQ ID NO: 18). In contrast, the amino acid sequence for the GenBank Accession No. Z32675 is translated from the C-terminal portion of the cDNA sequence of the HR gene. Begona indicates on page 7719 that there are 12 nucleotide differences between the genomic sequence of the HR gene and the RT-PCR clone (i.e., cDNA clone) (See Appendix A; 12 nucleotide changes are circled). Applicants submit that 3 of the 12 nucleotide changes result in amino acid changes in the portion of the sequence responsible for encoding the C-terminal portion of the HR protein (i.e., amino acids 490-1182) (See Appendix A and B; amino acid changes are designated by rectangles in both appendices). Therefore, Applicants submit that SEQ ID NO: 17 is not expected to have 100% homology with Genbank Accession No. Z32675.

3) The Preliminary Amendment filed on October 20, 2009 has also been objected to under 35 U.S.C. 132(a) for introducing new matter into pages 27-28 of the specification. Specifically, the Examiner asserts that there is no support for amending the nucleotide positions to 2165, 2600, and 2915. Applicants traverse this objection for at least the reasons set forth herein.

Applicants submit that the nucleotide positions of 2166, 2611, and 2916 set forth on page 28 of the originally-filed specification are based on the published sequence in

Figure 2 of Begona (See page 27, lines 31-33 and page 28, lines 15-19). Applicants submit that these nucleotide positions were mistakenly amended to 321, 756, and 1076 respectively, on October 24, 2005. Recently, Applicants determined that nucleotide positions 321, 756, and 1076 were mistakenly amended to correlate with the sequence numbering in the replacement sequence listing; thus, nucleotide positions 321, 756, and 1076 are incorrect. Applicants have further determined that the original nucleotide positions of 2166, 2611, and 2916 are also incorrect. For example, nucleotide position 2166 (currently part of the record as 321) should be 2165; nucleotide position 2916 (currently part of the record as 1076) should be 2915; and nucleotide position 2611 (currently part of the record as 756) should be 2600. Regarding the amendment of nucleotide position 2166 (currently part of the record as 321) to 2165, Applicants submit that one of ordinary skill in the art would recognize that the nucleotides were mistakenly counted to arrive at 2166 instead of 2165 for AGC by counting the nucleotide positioning in Figure 2 of Begona. One of ordinary skill in the art would arrive at this conclusion because there is no other AGC near position 2166. Regarding the amendment of nucleotide position 2916 (currently part of the record as 1076) to 2915, Applicants submit that one of ordinary skill in the art again would recognize that the nucleotides were mistakenly counted to arrive at 2916 instead of 2915 by counting the nucleotide positioning in Figure 2 of Begona. One of ordinary skill in the art would arrive at this conclusion because there is no other CCT near position 2916. The closest CCT is at nucleotide position 2921, which is farther away from the original nucleotide position of 2916. Regarding the amendment of nucleotide position 2611 (currently part of the

record as 756) to 2600, Applicants submit that one of ordinary skill in the art would recognize that a typographical error was made resulting in 2611 instead of 2600 by counting the nucleotide positioning in Figure 2 of Begona. One of ordinary skill in the art would arrive at this conclusion because there is no other GAC near position 2611. The closest GAC is at nucleotide position 2576, which is too far away from the original nucleotide position of 2611. Thus, Applicants submit that the amended nucleotide positions 2165, 2600, and 2915 are not new matter but are merely corrections of typographical errors; errors that would have been recognized as such by those skilled in the art, the corrections to which could have been logically determined.

Hence, Applicants respectfully submit that the objection to the amendments made to the nucleotide positions on page 28 is obviated and request the withdrawal of the objection and entry of the amendments filed on October 20, 2009.

#### **B) Rejection of Claims 1-2 under 35 U.S.C. § 101**

Claims 1-2 have been rejected under 35 U.S.C. § 101 because the Examiner asserts that the claimed invention is not supported by either a specific asserted utility or a well established utility. Applicants respectfully disagree.

35 U.S.C. § 101 states:

[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent thereof.

As set forth in MPEP 2107.02(VII),

[t]here is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted

utility, therapeutic or otherwise. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965). Nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty. *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980) (reversing the Board and rejecting Bowler's arguments that the evidence of utility was statistically insignificant. The court pointed out that a rigorous correlation is not necessary when the test is reasonably predictive of the response). See also *Rey-Bellet v. Englehardt*, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974) (data from animal testing is relevant to asserted human therapeutic utility if there is a "satisfactory correlation between the effect on the animal and that ultimately observed in human beings"). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true.

Applicants submit that the present invention includes a composition comprising a mouse hairless (HRt) protein – human interacting partner protein complex ("HRt-IP complex").

More specifically, the "HRt-IP complex" refers to at least one molecule of HRt associated with at least one molecule of interacting partner, under physiological conditions of ionic strength, temperature, pH, and the like (specification, page 6, lines 24-26).

Applicants further submit that the specific utility of the present invention is to use the HRt protein -human interacting partner protein complexes, such as HRt-IP complexes that comprise Homo Sapiens Ubiquitous Receptor, for screening and/or

discovery of compounds having agonist or antagonist activity for binding to the hairless protein interacting partner complex. This utility finds support in Examples 2 and 3.

Once identified, these agonist or antagonist compounds are further tested to determine whether they convey one or more of the following benefits to mammalian skin: improved epidermal barrier function and hydration, cellulite reduction, enhanced barrier repair, prevention as well as reversal of skin wrinkling and hair growth retardation (specification, page 8, lines 13-18).

Thus, Applicants submit that the claimed composition is supported by a specific asserted utility because one of ordinary skill in the art would recognize that the asserted utility of the claimed composition is true and useful. Hence, Applicants respectfully submit that the rejection to claims 1-2 under 35 U.S.C. § 101 is obviated and request that the rejection be withdrawn.

**C) Rejection of Claims 1-2 under 35 U.S.C. §112, first paragraph**

Claims 1-2 have been rejected under 35 U.S.C. §112, first paragraph for a lack of enablement. Specifically, the Examiner asserts that one of ordinary skill in the art would not know how to use the claimed invention because it is not supported by a specific or substantial utility. As set forth in *Section B*, the present invention is supported by a specific utility related to using the hairless protein interacting partner complexes for screening and/or discovery of agonist and antagonist compounds adapted to provide material beautification and improvement benefits to mammalian skin.

Hence, Applicants respectfully submit that the rejection to claims 1-2 under 35 U.S.C. §112, first paragraph is obviated and request that the rejection be withdrawn.

**D) Rejection of Claims 1-2 under 35 U.S.C. § 112, first paragraph**

Claims 1-2 have been rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. Specifically, the Examiner asserts that new matter is introduced because the claims are drawn to a composition comprising a mouse HRt protein, which is not supported in the specification. As set forth in *Section A*, the C-terminal portion of the HR protein ("amino acid sequence of HRt protein") represented by SEQ ID NO: 17 is not new matter because the sequence is disclosed in Begona, which Applicants assert was properly incorporated by reference under 37 C.F.R. § 1.57. In addition, amended nucleotide positions 2165, 2600, and 2915 do not constitute new matter for at least the reasons set forth in *Section A*.

Hence, Applicants respectfully submit that the rejection to claims 1-2 under 35 U.S.C. § 112, first paragraph is obviated and request that the rejection be withdrawn.

**E) Rejection of Claims 1-2 under 35 U.S.C. §102(e)**

Claims 1-2 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by U.S. Patent Application Publication 2004/0086945 to Sreekrishna *et al.* (hereinafter "the '945 publication"). Applicants traverse this rejection for at least the reasons set forth herein.

As noted by the Examiner (Office Action, page 13), and as set forth in MPEP 706.02(b), a rejection based on 35 U.S.C. 102(e) can be overcome by filing an affidavit



or declaration under 37 C.F.R. 1.132 showing that the referenced invention is not by "another."

In this regard, Applicants submit herewith the Declaration of Kotikanyadanam Sreekrishna under 37 C.F.R. § 1.132. As set forth in the Declaration, Mr. Sreekrishna is a sole inventor of the subject matter related to compositions comprising a complex of mouse HRt protein and human ubiquitous receptor set forth in the subject application and also disclosed in United States Patent Application Publication 2004/0086945 ('945 application"). Therefore, the '945 application, cited by the Examiner to reject claims 1-2, is not by "another," and not prior art under 35 U.S.C § 102(e).

Hence, the Applicants respectfully submit that the rejection is obviated and requests that this rejection be withdrawn.

**Conclusion**

Applicants respectfully submit that claims 1-2 of the Subject Application are novel and non-obvious over the prior art of record and are in proper form for allowance. In view of the Remarks submitted herein, Applicants respectfully submit that the Subject Application is in condition for allowance. Accordingly, reconsideration of the claims and allowance of the claims at an early date are earnestly solicited.

If the undersigned can be of assistance to the Examiner in addressing any additional issues to advance the application to a condition of allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,

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Date

  
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